UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,681	05/10/2001	Alexander James Wigmore	2001-0878.ORI	7056

7590 09/09/2002

Mark J. Burns
1130 TCF Tower
121 South Eighth Street
Minneapolis, MN 55402

EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/09/2002 16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/831,681	WIGMORE, ALEXANDER JAMES	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *10-15 and 17-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statement filed 07/12/01, and Election filed 06/10/02.

Election/Restriction

1. Applicant's election with traverse of group I, claims 1-9, and 16 invention in Paper No. 5, 06/10/02 is acknowledged.

2. Claims 10-15, 17-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Applicant's arguments filed 06/10/02 have been fully considered but they are not persuasive.

Requirement for restriction practice are set forth in MPEP§803.

There are two criteria for a proper requirement for restriction between patentable distinct inventions:

I. The inventions must be distinct as claimed (see MPEP§806.05-806.05(I)); and

ii. There must be a serious burden on the examiner if restriction is not required (see MPEP§803.02, 806.04(a)-(j), 808.01(a) and 808.02).

The traversal is on the ground that claims 1, 8, and 12 recite an oral drug delivery composition comprising a chromone, and therefore, all the claims can and should be examined

together, and that the examiner will necessarily search for and evaluate the subject matter of all the claims. This is not found persuasive. Nonetheless, claims 8, 9, and 16 previously withdrawn from consideration as a result of a restriction requirement, now subject to being rejoined. All other claims are not rejoined because claim 10 is a pellet or spherical, and claim 12 require amphoteric surfactant, which do not have to be in claims 1 or 8. Furthermore, method and product claims are statutorily distinct categories of invention, and the particular method claimed is distinct from the particular product claimed because there is an alternative method of making/using the product. Therefore, there is no reason why a search for the method must include a search for the product as well.

Distinctness between a process of making and the product made is shown if "the product as claimed can be made by another materially different process." MPEP§806.05(f). In the restriction requirement, the examiner set forth several "materially different processes" by which the claimed product could be made.

A serious burden on the examiner is shown according to the criteria of MPEP§808.02, where one of the following must be supported by appropriate explanation:

I. Separate classification thereof:

This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search,. Patents need not be cited to show separate classification;

ii. A separate status in the art when they are classifiable together; and

iii. A different field of search.

In the restriction requirement dated 05/06/02, the examiner set forth separate classification for the four inventions to which claims were presented. Applicant has not alleged that either product or method claims were improperly classified. Nor has applicant alleged that the classifications set forth are not "separate classifications." Thus, requirement 2 and 3 of MPEP§803 are met. For these reasons set forth above, the restriction requirement is proper.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

4. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.

(b) Cross-Reference to Related Applications.

© Statement Regarding Federally Sponsored Research or Development.

(d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).

(e) Background of the Invention.

1. Field of the Invention.

2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.

(g) Brief Description of the Several Views of the Drawing(s).

(h) Detailed Description of the Invention.

(I) Claim or Claims (commencing on a separate sheet).

(j) Abstract of the Disclosure (commencing on a separate sheet).

(k) Drawings.

(l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5, 7, and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Hewlett Healthcare Limited WO 98/51300.

Hewlett teaches oral formulations comprising 100-1000 mg chromone and excipients, such as starch, microcrystalline cellulose, methylcellulose, and one or more of pharmaceutically acceptable materials (pages 3, 10, & 15). The formulation can be in an enteric coated granule, pellet, capsule, or tablet (pages 12-13). The release rate is disclosed in pages 5-6.

Claims 1-3, 5, 7, and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Wigmore GB 2 324 962.

Wigmore teaches orally administered formulations comprising 100-1000 mg chromone and excipients, such as starch, microcrystalline cellulose, methylcellulose, and one or more of pharmaceutically acceptable materials (abstract, and pages 10-15). The formulation can be in an enteric coated granule, pellet, capsule, or tablet (pages 6-13). The release rate is disclosed in page 6.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hewlett and Wigmore.

Hewlett and Wigmore are relied upon for the reasons stated above. In the case that applicant can overcome the above 102(a) rejections, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to obtain the claimed invention because the references accrued the same result desired by the applicant, i.e., orally administered formulation comprising chromone for the treatment of allergic conditions.

Claims 6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hewlett/Wigmore and Pharmacia AB WO 85/00015.

Hewlett/Wigmore is relied upon for the reason stated above. The references do not teach the ratio between disintegrant and active agent.

Pharmacia teaches enteric coated tablet formulation comprising 100 mg disodium cromoglycate , and 98 mg Avicel® (abstract, and page 17). Thus, it would have been prima facie obvious for one of ordinary skill in this art to modify the oral formulation of Hewlett/Wigmore using the coated tablet having the weight ratio between disintegrant and active agent in view of the teaching of Pharmacia. The reason for this modification is to obtain an enteric coated oral tablet, which is resistant to gastric juice and contains an antiallergic substance.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jenkins et al., Newman et al., Orr et al., and Watts et al. are cited as being of interest for the teachings of enteric coated oral dosage form containing chromone useful for the treatment of allergic conditions.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600